

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB178 trade name]*

Isoniazid 100 mg tablets

[TB178 trade name] *, manufactured at Macleods Pharmaceuticals Limited, Daman, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 23 April 2008.

[TB178 trade name] * is indicated for tuberculosis. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient of [TB178 trade name] is isoniazid.

The efficacy and safety of isoniazid is well established based on extensive clinical experience in the treatment of tuberculosis.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of isoniazid in antituberculosis, the team of assessors advised that [TB178 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB178 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB178 trade name]*:

| Initial acceptance | Date | Outcome |
|---|---|-------------------------|
| Status on PQ list | 23 April 2008 | listed |
| Quality | 14 March 2008 | MR |
| Bioequivalence | 29 March 2007 | MR |
| Safety, efficacy | NA | NA |
| GMP (re-)inspection | | |
| API | 14 October 2006 | Waived (only source) |
| FPP | 20 June 2007 | MR |
| GCP/GLP (re-)inspection | | |
| API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard] | GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification | |

| | | |
|------------------------|--------------|----|
| Requalification | 30 July 2019 | MR |
|------------------------|--------------|----|

The table represents the status of relevant completed activities only.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.